

**THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

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IN RE COLUMBIA UNIVERSITY	)	)
PATENT LITIGATION	)	MDL No. 1592 (MLW)

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**PLAINTIFFS WYETH AND GENETICS INSTITUTE LLC'S STATUS REPORT AND  
MEMORANDUM OF REASONS IN SUPPORT OF PLAINTIFFS' MOTION FOR  
LEAVE TO FILE AN AMENDED AND SUPPLEMENTAL COMPLAINT**

On November 5, 2004, the Court issued its Memorandum and Order (the “Memorandum and Order”) granting defendant The Trustees of the Columbia University in the City of New York’s (“Columbia”) emergency motion to dismiss the declaratory judgment claims in the multidistrict litigation cases. The Court ordered the parties to file a report by December 6, 2004 addressing several specific issues. Plaintiffs Wyeth and Genetics Institute LLC (the successor of Genetics Institute, Inc.) (collectively referred to herein as “Wyeth” unless specifically stated otherwise) respectfully submit this report on the status of its case pursuant to the Court’s order. Wyeth simultaneously moves, pursuant to Rule 15 of the Federal Rule of Civil Procedure, for leave to amend and supplement their Complaint, adding four claims and supporting information. These four new claims are separate and distinct from the previously asserted claims of invalidity and unenforceability of U.S. Patent No. 6,455,275 (“the ‘275 patent”). There has been no undue delay in seeking to add these claims to Wyeth’s complaint, and as discovery has only been conducted on one issue and is not impacted by the addition of these claims, Columbia will not be

unduly prejudiced by the addition of these claims. Therefore, this Court should grant Wyeth's request for leave to file an amended and supplemental Complaint to add these four claims.

## **I. STATUS OF WYETH'S CASE AND CLAIMS**

### **A. Status of Claims from Wyeth's Original Complaint**

The Court ordered the parties to state whether they agree that the claims listed in Columbia's Proposed Order should all be dismissed based upon the Memorandum and Order. Wyeth agrees that claims 1-3 and 7-11 of its original complaint should be dismissed in light of the Court's Memorandum and Order. Wyeth disagrees with Columbia that claims 4-6 should also be dismissed pursuant to the Court's Memorandum and Order. All three of these claims seeks the return of funds previously paid to Columbia by Wyeth under the License Agreement dated July 31, 1990 between Columbia and Genetics Institute, Inc., the predecessor of plaintiff Genetics Institute, LLC (the "License Agreement"), and are unaffected by Columbia's covenant to not seek further enforcement of the '275 patent as currently issued nor by the Court's Memorandum and Order. With respect to recovery of funds already paid by Wyeth to Columbia, claims four, five and six of Wyeth's complaint are not Declaratory Judgment actions, but are instead direct actions for past wrongs committed by Columbia. As such, they do not implicate the issues of actual case or controversy addressed in the Court's Memorandum and Order, and thus remain pending in this litigation. It is important to note that while Columbia has suggested it would return certain fees and royalties, it has not actually done so. Until Columbia returns all inappropriately obtained funds, Wyeth's claims must remain alive, or Columbia will be under no obligation to return these funds in the future.

Claim four of Wyeth's complaint asserts that Columbia's U.S. Patent 6,455,275 ("the '275 patent") is invalid and unenforceable due to the reasons described in detail in the complaint, including the fact that the '275 patent claims are invalid because they are identical to, or obvious

variants of, the inventions claimed in Columbia's patents 4,399,216 ("the '216 patent"), 4,634,665 ("the '665 patent"), and 5,179,017 ("the '017 patent"); the '275 patent is invalid for failing to satisfy one or more of the statutory conditions of patentability set forth in 35 U.S.C. §§ 102, 103 and 112; and the '275 patent is unenforceable due to prosecution laches and inequitable conduct. As detailed in Wyeth's complaint, Wyeth has previously paid Columbia funds pursuant to the License Agreement based upon the '275 patent application. Wyeth is entitled to return of these funds. Neither Columbia's covenant not to assert the '275 patent as currently issued, nor the Court's Memorandum and Order, affects Wyeth's claim for return of these previously paid funds.

Claim five of Wyeth's complaint seeks a declaration that the License Agreement does not require payment of royalties or fees based upon pending patent applications. Claim five also seeks return of funds paid by Wyeth between the expiration of the original three patents on August 16, 2000 and the issuance of the '275 patent on September 24, 2002. This claim is based upon the terms of the License Agreement, and is unrelated to claims of invalidity or unenforceability of the '275 patent. As long as Columbia fails to return the funds previously paid by Wyeth after August 16, 2000, claim five represents a direct, valid claim against Columbia, and Wyeth is entitled to pursue claim five.

Claim six of Wyeth's complaint alleges that the '275 patent is unenforceable due to patent misuse because Columbia has unlawfully sought to extend its patent monopoly by claiming Wyeth owes funds under the License Agreement on the basis of the '275 patent application. Claim six therefore seeks a declaration that the '275 patent is unenforceable due to patent misuse and seeks recovery of funds paid after the expiration of the original patents on August 16, 2000. As long as Columbia fails to return the funds previously paid by Wyeth, claim

six represents a direct, valid claim against Columbia. Accordingly, claim six is ripe for adjudication and Wyeth is entitled to pursue this claim.

**B. Status of Settlement, Stay and Schedule**

Although during the October 6<sup>th</sup> hearing, Columbia represented to the Court that it was prepared to settle the case, this has not yet occurred. As pointed out by Wyeth during the October 6<sup>th</sup> hearing, Columbia owes Wyeth money due to an overpayment of royalties under its license to the Axel patents. Wyeth has requested that Columbia return this money, but to date no money has been returned.

Wyeth therefore proposes that the Court set a date certain by which the parties settle and the overpayment issue is resolved, or Wyeth files its amended complaint. Wyeth suggests that such a deadline would focus the parties to resolve their differences if possible, and would avoid wasting judicial resources. If an amended complaint is filed, it will be clear that settlement was impossible.

Wyeth therefore proposes that the Court set January 31, 2005 as the last day for Wyeth to amend its complaint. If settlement is impossible and the amended complaint is filed, Wyeth proposes a short discovery period (about 3 months), and an early trial date. As this case was originally filed in this Court, there is no issue regarding remand regardless of the status of the multidistrict litigation, and this case should be allowed to proceed.

**II. WYETH'S MOTION TO AMEND AND SUPPLEMENT ITS COMPLAINT**

**A. Wyeth seeks to amend and supplement its complaint by adding the following claims:**

1. Breach of Contract for Improper Termination of the License Agreement;
2. Return of Royalty Overpayment and Breach of the Implied Duty of Good Faith and Fair Dealing;

3. Abuse of the Judicial Process;
4. Violation of MASS.GEN.LAWS c.93A, §§ 2 and 11.

These claims are listed as Claims for Relief Twelve (12) - Fifteen (15) in Wyeth's Proposed Amended and Supplemental Complaint attached to Wyeth's Motion for Leave to File an Amended and Supplemental Complaint.

#### **B. Background**

Wyeth filed its complaint against defendant Trustees of Columbia University in the City of New York ("Columbia") on August 20, 2003 in the District of Massachusetts. The complaint contained eleven claims for relief alleging, *inter alia*, the invalidity and unenforceability of U.S. Patent No. 6,455,275 ("the '275 patent") assigned to Columbia; breach of the July 31, 1990 license agreement between Genetics Institute, Inc. and Columbia (the "License Agreement," now assigned to Wyeth); breach of Columbia's letter agreement with HHS concerning the Axel patents at issue; breach of the implied duty of good faith and fair dealing toward Wyeth by Columbia; and the existence of an implied license to the '275 patent.

At about the same time that Wyeth filed its complaint, several additional cases were filed by other licensees alleging that the '275 patent was invalid and unenforceable. On October 31, 2003, Columbia sued its licensees Johnson & Johnson and Ares Trading S.A. for a declaration that the '275 patent is valid and enforceable, and for breach of contract, alleging that these companies owed royalties on the '275 patent.

When the companies that filed suit against Columbia attempted to move their cases forward, Columbia stalled. Columbia refused to permit discovery and sought to stay various cases while it filed motions under 28 U.S.C. § 1404 to transfer venue of each of the cases to the Northern District of California. Eventually, Columbia abandoned its venue motions, and moved

for multidistrict transfer of all pending cases to the Northern District of California under 28 U.S.C. § 1407.

On April 8, 2004, the Judicial Panel on Multidistrict Litigation (“JPML”) issued a Transfer Order, granting Columbia’s request to consolidate the several cases for pretrial proceedings but denying its request to transfer the actions (the “MDL cases”) to the Northern District of California. Instead, the JPML ordered transfer of the MDL cases to the District of Massachusetts, assigning them to the Honorable Mark L. Wolf (the “MDL Court”). Since that date, the litigation has proceeded in this District.

While this litigation has been pending, Columbia has engaged in actions designed to prolong and eventually prevent judicial determination of the invalidity and unenforceability of the ‘275 patent. As detailed below, Columbia has abused the judicial process and the procedures for reexamination and reissue of patents in the United States Patent and Trademark Office (the “PTO”). As a result of Columbia’s actions and conduct, Wyeth seeks to add claims for abuse of judicial process, breach of contract for improperly terminating the License Agreement, and violation of MASS.GEN.LAWS c. 93A, §§ 2 and 11.

In addition, Columbia has repeatedly refused to return an almost \$2.3 million royalty overpayment made from Wyeth to Columbia. The outrageous behavior and dilatory tactics exhibited by Columbia in connection with this entire litigation have led to the conclusion that litigation is necessary to obtain the return of Wyeth’s money. Accordingly, Wyeth seeks to add a claim for return of this royalty overpayment in the amount of \$2,273,465.33 plus interest.

### **C. Columbia’s Actions in Connection with this Litigation**

#### **1. Reexamination and Reissue Proceedings**

On February 25, 2004, a third party, the Public Patent Foundation, filed a Request for Ex Parte Reexamination of the ‘275 patent on the grounds of double patenting. Columbia took no

action in response. It did not file its own reexamination request, it did not file a reissue application, and it did not retract its demands to the MDL plaintiffs for payment of royalties under the '275 patent.

Columbia continued to do nothing when the PTO granted Public Patent Foundation's Request for Reexamination on May 6, 2004. While Columbia failed to take action in response to the Reexamination announcement, on May 27, 2004, this Court issued an Order that, among other things, directed the parties to address the implications of the PTO's decision to reexamine the '275 patent.

Still wanting to delay the issue as long as possible, on June 10, 2004, over a month after the PTO's grant of reexamination, Columbia moved for a stay of the MDL proceedings based on the reexamination proceeding and its intent to file a reissue application with the PTO. Columbia filed its reissue application, which seeks to broaden the scope of the claims in the '275 patent, on June 18, 2004.

Columbia's filing came a mere three months before the expiration of the two-year window for seeking a broadening reissue. In its reissue application, Columbia seeks to expand the scope of the '275 patent by adding no fewer than seventeen new, broader claims and by amending its existing claims to enlarge their breadth as well. In other words, after waiting to file the reissue application until nearly two years after issuance of the '275 patent (and more than twenty-four years after filing the original patent application), Columbia is using the reissue application on the '275 patent to begin prosecuting new, broader claims. Columbia tries to justify the reopening of prosecution, some twenty-four years after filing its original application and after having obtained dozens of claims in three earlier issued patents, on the ground that it "failed to obtain the full scope of protection" for its 1980 invention.

Columbia's reissue application is the next chapter in its attempt to string out its patent prosecution. In the ex parte PTO reissue and reexamination proceedings, Columbia has substantial control over the length of the process. Columbia has already begun to exploit the numerous opportunities for delay provided by the rules for reexamination and reissue.

For example, at a June 22, 2004 hearing, in seeking to persuade the Court that reissue and reexamination would provide an efficient resolution of plaintiff's claims, Columbia told the Court that "it's very common to ask for reissue, and that's why there's a procedure to merge the two proceedings when someone asks for a reexamination. But it [sic.] both happened together on the same track by the same examiner so nothing gets slowed down. That's what we want to happen. We want to get this done quickly in the Patent Office too." June 22, 2004 Hearing Transcript, p. 90-91, attached at Tab A. A true copy of the transcript of the July 22, 2004 hearing is attached as Exhibit 7 to the Amended and Supplemental Complaint.

On July 7, 2004, however, just over two weeks later, and without informing the Court, Columbia filed a request to stay the reexamination of the '275 patent until completion of the reissue proceedings which it did not initiate until almost two years after the '275 patent issued. In its request to stay the reexamination, Columbia stated that "a merger of the two proceedings is not the preferred approach because in the above-identified reexamination, Patentees will not be permitted to obtain the broadened claims which Patentees are seeking, and are permitted to obtain, in their reissue application." Columbia also maintained that merger would be inappropriate because the obviousness-type double patenting issues that the Public Patent Foundation proposed for consideration on reexamination will be resolved on the reissue proceedings that Columbia initiated. If Columbia's request to stay the reexamination is allowed, the reexamination will not even begin until after the conclusion of the reissue proceedings.

In other words, Columbia not only plans to take the maximum time to replay and fine-tune its previous seven-year prosecution of the '275 patent, it proposes that when the reissue concludes, the patent will **then**, and **only** then, enter the reexamination proceeding initiated by the PTO in response to the Request for Ex Parte Reexamination filed by the Public Patent Foundation.

**2. Columbia's Improper Termination of the License Agreement with Wyeth**

Despite the fact that the original Axel patents expired in August 2000, Columbia improperly demanded that Wyeth pay royalties based on pending patent applications, and repeatedly threatened to terminate the License Agreement.

On February 27, 2002, almost two years after the Axel patents expired, in response to Columbia's demands for royalties, Wyeth stated that it would pay royalties only on products that, but for the license, would infringe a valid patent. Columbia pressed its demands and threatened to terminate the license, insisting that, contrary to the plain language of the contract, royalties were owed based on pending patent applications. Columbia maintained this unreasonable position for two years. Not until well into this litigation, faced with plaintiffs' claims for patent misuse, that Columbia backed down, and disclaimed any right to royalty payments made pursuant to a pending application.

Simultaneously, on or about March 2004, although in the midst of negotiations with Wyeth to schedule an audit, Columbia terminated Wyeth's license agreement, not for failure to pay royalties based on pending patent applications as threatened for years, but for alleged failure to pay royalties and fees under the '275 patent and alleged failure to provide reports for unpaid royalties. Ignoring Wyeth's repeated requests for clarification of the grounds for termination, to allow opportunity to cure, Columbia terminated Wyeth's license on these newly stated grounds.

Months after purporting to terminate the license for failure to pay royalties and fees under the '275 patent and failure to provide reports for unpaid royalties, Columbia again changed positions. On September 1, 2004, in an attempt to deny this court jurisdiction, Columbia filed a vague, craftily worded "covenant not to sue" under the pre-reissue '275 patent for certain limited products. The covenant was so carefully worded and carved out so many exceptions that it was the subject of a series of letters following its filing in which Columbia purported to "clarify" the terms of the covenant - being careful to retain the right to sue for any products and processes introduced by plaintiffs after September 1, 2004 and the right to sue on any patents subsequently issued on pending patent applications.

On September 2, 2004, Columbia filed its Emergency Motion to Dismiss. In a letter to the Court on September 3, 2004, Columbia stated that its previous termination of plaintiff's license agreements, including the License Agreement with Wyeth, were "ineffective." The Court scheduled a telephonic hearing on September 9, 2004, during which Columbia's counsel stated that the termination of the license for failing to pay royalties under the '275 patent was withdrawn.

Subsequently, on September 13, 2004, Columbia informed Wyeth that its licenses were in fact terminated, however, because of an alleged failure to pay all annual fees. Columbia has thus extracted money from one or more plaintiffs in this litigation, as well as other companies in the industry, relying on license agreements that have been terminated, seemingly reinstated and then in certain cases, including Wyeth's, terminated again.

Columbia's conduct in terminating and then re-terminating the License Agreement is particularly outrageous in light of the fact that the amount of fees that Columbia claims Wyeth owes under the License Agreement is a mere fraction of the amount that Columbia owes Wyeth.

As detailed below, in the course of paying royalties under its license to the Axel patents, Wyeth inadvertently overpaid Columbia by about \$2.3 million. Although Wyeth alerted Columbia to this error at least as of February 2002, Columbia has never returned the money. While wrongfully retaining nearly \$2.3 million of Wyeth's money for years, Columbia purports to justifiably terminate Wyeth's license based on less than \$100,000 in fees purportedly owed.

### **3. Wyeth's Overpayment of Royalties to Columbia**

Section 1(d) of the License Agreement requires that royalties be paid on any product "covered by a claim of" the licensed patents. The plain meaning of this term requires that royalties only be based on acts that would be infringing in the absence of the patent license. In addition, "covered by" is a term commonly used in the patent licensing field and is understood to mean royalties based on acts that would be infringing in the absence of the patent license. Thus, the License Agreement requires only that royalties be paid whenever activities of Wyeth, such as manufacture, use, sale or importation of a product using materials and/or produced by a process claimed in the Axel patents would infringe but for the patent license.

In early 2002, Wyeth investigated the calculation of royalty payments made to Columbia under the License Agreement. It was discovered that no royalties were ever due Columbia with respect to Wyeth's ReFacto® product because with respect to ReFacto®, Wyeth never engaged in acts which would be infringing in the absence of the patent license. All ReFacto® products sold in the United States as of February 2002 were produced in Europe utilizing a transfection approach unpatented (and unpatentable) in Europe. None of this material was sold in the United States prior to the expiration of the Axel patents in August 2000. Thus, no royalties were ever due Columbia with regard to ReFacto®.

Despite this, due to error, Wyeth mistakenly paid Columbia a total of \$2,273,465.33 in royalties on ReFacto®<sup>1</sup>. Wyeth informed Columbia of this error at least as of February 27, 2002, yet Columbia has repeatedly refused to return Wyeth's money. Wyeth is entitled to a refund of its mistakenly paid royalties.

#### **D. ARGUMENT**

Motions for leave to amend are governed by Fed. R. Civ. Proc. 15(a), which states that such leave "shall be freely given when justice so requires." Motions for leave to supplement pleadings are covered by Rule 15(d), which provides that a court "may, upon reasonable notice and upon such terms as are just, permit the party to serve a supplemental pleading setting forth transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented." The Supreme Court has expressed a strong preference for allowing amendments to pleadings:

Rule 15(a) declares that leave to amend "shall be freely given when justice so requires"; this mandate is to be heeded. See generally, 3 Moore, Federal Practice (2d ed. 1948) 1508, 1510 . . . In the absence of any apparent or declared reason--such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.--the leave sought should, as the rules require, be "freely given."

Foman v. Davis, 371 U.S. 178, 182 (1962). See also Vargas v. McNamara, 608 F.2d 15, 18 (1<sup>st</sup> Cir. 1979); Tingley Systems, Inc. v. CSC Consulting, Inc., 152 F.Supp.2d 95, 116 (D.Mass. 2001).

Given the behavior exhibited by Columbia throughout, and even preceding, this litigation, justice requires that Wyeth be allowed to add claims for breach of contract, abuse of

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<sup>1</sup> Wyeth paid a total of \$1,803,146.36 in cash to Columbia, and offset \$470,318.97 in funds which were returnable to Wyeth in connection with royalty payments on Wyeth's Neumega product, for a total of \$2,273,465.33.

judicial process, and violation of MASS. GEN. LAWS c. 93A. These claims all relate to Columbia's conduct in connection with this suit and the '275 patent and there will be significant overlap between these claims and claims 4-6 originally pled by Wyeth, which are still outstanding following the Court's grant of Columbia's emergency motion to dismiss. These new claims are all based on acts by Columbia that have occurred since the filing of Wyeth's complaint, and there has been no undue delay in bringing these claims.

Columbia's refusal to return Wyeth's royalty overpayment has no legitimate basis, and is merely another attempt by Columbia to pressure Wyeth into paying an unjustified, exorbitant amount to Columbia to settle this case and take a license to Columbia's invalid and unenforceable patents. Justice requires that Wyeth be allowed to add its claim seeking refund of this overpayment, as it relates to the License Agreement, and the '275 patent at issue in this litigation. Wyeth informed Columbia of the overpayment as early as February 2002, and the parties have discussed the return of the money on several occasions since then. Wyeth was hopeful that Columbia would comply with its obligation to return this money, and that litigation on this point could be avoided. However, given Columbia's actions in this litigation and in settlement negotiations, it is now clear that Columbia's refusal to return the overpayment is merely part of its strategy to attempt to improperly extract an unjustified, exorbitant settlement or monetary payment from Wyeth and the other plaintiffs. Accordingly, there has not been an undue delay in bringing this claim for overpayment of royalties, and the amendment should be allowed.

Columbia in no way will be prejudiced as a result of the addition of any of these claims to Wyeth's complaint. Only very limited discovery has taken place in this case, and all of it has been on double-patenting issues. The new claims do not expand the double-patenting issue at all

and Columbia is at no disadvantage having already taken this discovery. No other discovery has yet occurred, and Columbia will have a full opportunity to develop defenses to these new claims.

### **III. CONCLUSION**

For all the foregoing reasons, Wyeth respectfully requests that the Court order that claims four, five and six of Wyeth's complaint remain outstanding and are ripe for adjudication, and the Court grant Wyeth's motion for leave to amend and supplement its complaint to add new claims twelve to fifteen.

Dated: December 6, 2004

Respectfully submitted,

/s/ Eric J. Marandett  
One of the Attorneys for WYETH, and  
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